AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,886	03/26/2004	Marit Nilsen-Hamilton	19000.0058/P058	7776

24998 7590 01/04/2006

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L Street, NW
Washington, DC 20037

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,886	NILSEN-HAMILTON, MARIT	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4, 5-18, drawn to a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to a second target, classifiable in class 536, subclass 24.5. This group is subject to a further restriction as per below.

II. Claim 2, drawn to a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target inhibits the binding of at least one regulated aptamer to a second target, classifiable in class 536, subclass 24.5.

III. Claim 19-41, drawn to a method for detecting a plurality of targets comprising providing an allosteric probe containing an allosteric regulator linked to at least one regulated aptamer, contacting the probe with a first target wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least the second target, classifiable in class 435, subclass 6. This group is subject to a further restriction as per below.

IV. Claims 43-49, drawn to a method of selectively targeting a chemotherapeutic agent to a target cell comprising providing an allosteric probe containing an allosteric regulator and a regulated aptamer, contacting the allosteric regulator

with the target cell enhances the binding of the regulated aptamer to a toxic agent, classifiable in class 435, subclass 375.

V. Claims 43-49, drawn to a method of selectively targeting an antibody to a target cell comprising providing an allosteric probe containing an allosteric regulator and a regulated aptamer, contacting the allosteric regulator with the target cell enhances the binding of the regulated aptamer to a toxic agent, classifiable in class 435, subclass 375.

VI. Claims 43-49, drawn to a method of selectively targeting an antisense to a target cell comprising providing an allosteric probe containing an allosteric regulator and a regulated aptamer, contacting the allosteric regulator with the target cell enhances the binding of the regulated aptamer to a toxic agent, classifiable in class 435, subclass 375.

VII. Claims 50-52, drawn to a method of selectively targeting a tumor inhibiting drug to a prostate stem cell antigen expressing cell comprising contacting the prostate stem cell antigen expressing cell with an allosteric probe comprising an allosteric regulator capable of binding to the prostate stem cell antigen expressing cell enhancing the binding of the regulated aptamer capable of binding to CPI-0004Na, classifiable in class 435, subclass 375.

VIII. Claims 50-52, drawn to a method of selectively targeting a tumor inhibiting drug to a prostate stem cell antigen expressing cell comprising contacting the prostate stem cell antigen expressing cell with an allosteric probe comprising an allosteric regulator capable of binding to the prostate stem cell antigen expressing cell

enhancing the binding of regulated aptamer capable of binding to L-377202, classifiable in class 435, subclass 375.

IX. Claims 53-55, drawn to a method of selectively targeting an antibiotic to microorganism susceptible to the antibiotic comprising contacting the microorganism with an allosteric probe comprising an allosteric regulator capable of binding to a microorganism and a regulated aptamer capable of binding to an antibiotic, classifiable in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the allosteric regulator of group I enhances the binding of the regulated aptamer to a second target, which is materially different than the allosteric regulator of group II which inhibits the binding of a regulated aptamer to a second target. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used in a method of selectively targeting a chemotherapeutic agent to a target cell which is materially different than the method of detecting a plurality of targets using an allosteric probe as present in group III. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used to inhibit the binding of a regulated aptamer to a target, which is materially different than the method of selectively targeting a chemotherapeutic agent to a target cell using an allosteric probe as present in group IV. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used to

inhibit the binding of a regulated aptamer to a target, which is materially different than the method of selectively targeting an antibody to a target cell using an allosteric probe as present in group V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used in a method of screening for putative probes that bind to targets, which is materially different than the method of selectively targeting an antisense molecule to a target cell using an allosteric probe as present in group VI. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used to inhibit the binding of a regulated aptamer to a target, which is materially different than the method of selectively targeting a tumor inhibiting agent to a target cell using an allosteric

regulator that enhances the binding of the regulated aptamer to prodrug CPI-0004Na, as present in group VII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used to inhibit the binding of a regulated aptamer to a target, which is materially different than the method of selectively targeting a tumor inhibiting agent to a target cell using an allosteric regulator that enhances the binding of the regulated aptamer to prodrug L-3777202, as present in group VIII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the allosteric probe of group I can be used to inhibit the binding of a regulated aptamer to a target, which is materially different than the method of selectively targeting an antibiotic to a microorganism using an allosteric regulator that

enhances the binding of the regulated aptamer to the antibiotic as present in group IX. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and groups III-IX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the allosteric regulator of group I inhibits the binding of the regulated aptamer to a second target, which is materially different than the methods of groups III-IX which are drawn to methods of enhancing the binding of the regulated aptamer to a target. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups III-IX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of group III is drawn to detecting a plurality of targets using an allosteric probe and is not disclosed as capable of use in

the methods of groups IV-IX. The method of group IV is drawn to selectively targeting a chemotherapeutic agent to a target cell and is not disclosed as capable of use in the methods of group III and V-IX. The method of group V is drawn to selectively targeting an antibody to a target cell using an allosteric probe and is not disclosed as capable of use in the methods of groups III-IV and VI-IX. The method of group VI is drawn to selectively targeting an antisense to a target cell using an allosteric probe and is not disclosed as capable of use in the methods of groups III-V and VII-IX. The methods of groups VII-VIII are drawn to selectively targeting a tumor inhibiting drug to a prostate cell and are not disclosed as capable of use in the methods of groups III-VI and VIII-IX. The method of group IX is drawn to targeting an antibiotic to a microorganism and is not disclosed as capable of use in the methods of groups III-VIII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Furthermore, should applicants elect to prosecute group I or III, these groups are subject to further restriction as follows. Claims 8, 10, 17, 18, 20 and 33 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are

sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claims 8, 10, 17, 18, 20 and 33 specifically claims second targets capable of binding by the regulated aptamer as listed. Each second target is considered to be unrelated, since each second target claimed does not share a common core structure, each second target is functionally independent and distinct, and the second targets do not share a common utility. Furthermore, a search of more than one (1) of the targets claimed in claims 8, 10, 17, 18, 20 and 33 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed targets. In view of the foregoing, one (1) target is considered to be a reasonable number of targets for examination. Accordingly, applicants are required to elect a total of one (1) target from claims 8, 10, 17, 18, 20 and 33. Note that this is not a species election.

Furthermore, should applicants elect a specific second target of group I or III as a prodrug or an oligosaccharide, this group is subject to further restriction as follows. Claims 15-16 and 37-40 specifically claim prodrugs or oligosaccharides as listed. Each prodrug or oligosaccharide is considered to be unrelated, since each second target claimed does not share a common core structure and each target is functionally independent and distinct. Furthermore, a search of more than one (1) of the second targets claimed in claims 15-16 and 37-40 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed second targets. In view of the foregoing, one (1) target is considered to be a reasonable number of second targets for examination. Accordingly, applicants are required to elect a total of one (1) second target from claims 15-16 and 37-40. Note that this is not a species election.

Claims 9, 23 and 32 specifically claims first targets capable of binding by the allosteric regulator as listed. Each first target is considered to be unrelated, since each first target claimed does not share a common core structure, each first target is functionally independent and distinct, and the first targets do not share a common utility. Furthermore, a search of more than one (1) of the first targets claimed in claims 9, 23 and 32 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed first targets. In view of the foregoing, one (1) first target is considered to be a reasonable number of targets for examination. Accordingly, applicants are required to elect a total of one (1) first target from claims 9, 23 and 32. Note that this is not a species election.

Furthermore, should applicants elect a specific first target in group I or III as a prodrug or an oligosaccharide, this group is subject to further restriction as follows. Claims 11-14 and 34-36 specifically claim prodrugs or oligosaccharides as listed. Each prodrug or oligosaccharide is considered to be unrelated, since each target claimed does not share a common core structure and each target is functionally independent and distinct. Furthermore, a search of more than one (1) of the targets claimed in claims 11-14 and 34-36 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed targets. In view of the foregoing, one (1) first target is considered to be a reasonable number of targets for examination. Accordingly, applicants are required to elect a total of one (1) first target from claims 11-14 and 34-36. Note that this is not a species election.

Claim 42 link(s) inventions IV-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 42. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635

SEAN McGARRY
PRIMARY EXAMINER
1635